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Shaun Manne

PI - Signature

April 14, 1999

Date

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IMPACT OF BRCA1/2 TESTING ON MARITAL RELATIONSHIPS

INTRODUCTION

The *Impact of BRCA1/2 Testing on Marital Relationships* is a prospective longitudinal study designed to examine the impact of genetic testing for breast-ovarian cancer susceptibility on the marital relationships of women at risk as well as the impact upon the quality of life of their husbands. This study is a companion proposal to an ongoing, DOD-funded prospective study that is evaluating the outcomes of genetic testing for breast-ovarian cancer susceptibility on women from hereditary breast cancer families. This second study extends the ongoing DOD-funded study to examine the impact of genetic testing upon the marital relationship and the psychosocial impact on the spouse. Specific aims of this study are: 1) to evaluate the short- and long-term impact of BRCA1/2 testing on psychological distress (both general and cancer-specific) of husbands of participants in genetic testing programs; 2) to evaluate the short- and long-term impact of BRCA1/2 testing on the marital relationships of participants and husbands, and examine whether marital satisfaction is an early predictor of psychological morbidity among participants in genetic testing programs and their spouses; 3) to examine the association between spouse responses during the testing process and carriers' distress post-notification.

Background and Study Rationale

Recent molecular studies have led to the identification of a major breast-ovarian cancer susceptibility gene, called BRCA1 (Miki et al., 1994). About 5-10% of all breast cancer cases are attributed to inherited BRCA1 mutations. Healthy women who have inherited BRCA1 mutations have 80-90% lifetime risk of breast cancer and 40-65% risks of ovarian cancer (Easton et al., 1993). Among women who are affected with breast cancer, those with BRCA1 mutations are believed to have a 38% 10-year risk and a 65% cumulative risk of second primary breast cancers (Easton et al., 1995). A second susceptibility gene (BRCA2) is estimated to account for an additional 5% of breast cancer cases (Wooster et al., 1995) and is also associated with an elevated risk of ovarian cancer (Berman et al., 1996; Thorlacius et al., 1996). The prevalence of mutations in BRCA1 and BRCA2 is higher in certain subgroups of breast cancer patients, such as Jewish women, younger women and those with family histories of cancer.

Evaluations of the psychosocial impact of BRCA1/2 testing indicate that, although BRCA1/2 testing may not generate significant psychological morbidity (Lerman et al., 1996), a subset of gene mutation carriers may be vulnerable to test-related psychological distress (Croyle et al., 1997). As yet, nothing is known about the impact of BRCA1/2 testing on husbands of testing participants. Spouses may be vulnerable to psychological distress for several reasons. First, if the couple has children, the husband may worry about the threat of a possible altered breast cancer gene passed on to the children. If the couple is still planning on having children, the husband may have concerns about future childbearing. Indeed, our prior research suggests that concerns about implications for altered breast cancer gene passed on to children are important to high risk women (Lerman, et al., 1995) and that testing may impact on reproductive plans (Lerman, et al., 1994).

Second, a husband may worry about the later development of cancer in his wife. The expectation of caregiving to an ill spouse, as well as worry about possible loss of the wife to cancer may each cause distress. Third, if the wife is distressed by the risk notification, her distress is likely to be conveyed to her spouse and is likely to lead to the husband becoming distressed. Indeed, studies of cancer patients and their spouses have suggested that spousal distress levels are highly correlated (Northouse, 1988).

In addition to impacting husbands' distress, genetic testing may place strain on the marital relationship. Our pilot data indicate that most couples discuss decisions (e.g., whether or not to undergo testing). Difficulty in communication during these discussions can result in less satisfaction with the marital relationship for both partners. Our prior research among cancer patients suggests that, if the patient feels constrained in his or her ability to talk with the spouse about emotional concerns, this leads to decreased marital satisfaction and psychological distress for patients (Manne et al., 1997; Manne et al., 1997). A second source of marital strain may be the support-related interactions between women and their spouses. Individuals typically seek support from their spouses when they are distressed and unsupportive responses by spouses are a main determinant of marital dissatisfaction (Gottman et al., 1989). If genetic testing participants do not receive the expected spousal support, marital strain is likely. In addition, couples who begin the testing process with marital problems may be particularly vulnerable to increased marital strain when they receive notification of a genetic mutation. Most of the psychological literature dealing with families at high risk for breast-ovarian cancer focuses on either the affected individual or the person genetically at risk (Lerman et al., 1996; Croyle et al., 1997). Almost no attention has been paid to the spouse of the individual at risk or the spouse's response to notification of carrier status. There are a limited number of studies which examine the psychological impact on spouses of predictive testing programs for Huntington's disease (HD) which indicate that partners of HD carriers experience marital distress (Codori et al., 1994; Quaid et al., 1995; Tibben et al., 1993). Tibben et al. (1997) found that partners had similar patterns of psychological distress over a 6-month follow up compared to tested individuals. Both carriers and their partners evidenced distress returning to pretest levels over the 3 year follow-up. However, among noncarriers, different patterns were found for carriers and their partners. Whereas noncarriers' partners had significantly lower levels of intrusive thoughts and avoidance at the 3 year follow-up, the levels of intrusive and avoidant thoughts were at pre-test levels for noncarriers themselves. Partners of carriers who had children were more hopeless and distressed than partners without children, illustrating the important role of worries about children. Given that the illness course of HD is difficult and disease prevention is not possible, it is not known whether similar psychological responses occur among partners of BRCA carriers.

Significance of the Study

The findings of this current study will make contributions to the empirical literature as well as have implications for genetic testing programs. First, this study would quantify the impact on the spouse, and identify those spouses who are vulnerable to a poor psychological outcome after testing. Distressed spouses could be offered adjunctive psychological support during the testing

process. Second, if disclosure of test results causes marital strain, then participants might benefit from the inclusion of spouses in disclosure sessions or training in more effective methods of facilitating disclosure of results. Identification of couples "at risk" for marital and psychological strain during this process can be facilitated. Third, those participants with low levels of spousal support might be targeted for adjunctive therapies that bolster social support.

In addition, this research would have important implications for the way in which genetic counseling and testing programs are currently being conducted. If disclosure of results causes marital strain for some participants, then participants might benefit from the inclusion of spouses in disclosure sessions or training in more effective methods of facilitating disclosure of results to family members. If mutation carriers who have more distressed marriages at the onset of the testing process or carriers who perceive more constraints in their ability to talk with their husband about concerns related to breast cancer are particularly vulnerable to poor psychological outcomes, these participants can be identified early and these women can be offered adjunctive therapies that bolster social support from other sources, or offered marital counseling. The information provided by this study would assist genetic testing providers to anticipate and more effectively deal with problems that may arise in clinical genetics programs.

Preliminary Studies

Lerman et al. (1996) examined 279 members of breast-ovarian families and found that noncarriers of BRCA1 mutations showed significant decreases in depression compared to carriers and decliners of testing one month post-notification (Lerman et al., 1996). There were no significant changes in carriers or decliners. These results indicate that, at least in the short term, the majority of high risk individuals do not evidence significant psychological distress. However, there was variability in the distress measure, indicating that education or other psychological factors might contribute to differences in psychological impact of testing. This study also did not identify individual differences in responses to testing, including the impact on family relationships.

Manne conducted a pilot study of 20 high risk women participating in the genetic testing program for breast-ovarian cancer at Memorial Sloan-Kettering Cancer Center. Women were administered questionnaires pre-genetic counseling, one month post-genetic counseling and one month post-test notification (1/14 tested positive). Pre-counseling: 90% of women discussed the decision to seek testing with their spouses and sought spouse advice. On average, spousal advice was rated as having "somewhat" of a role in the testing decision. Most women planned to disclose results to their husbands (90%). On average, participants anticipated a little difficulty in sharing results and felt husbands would be "somewhat" supportive during the discussion of test results. Post-counseling results indicated that most participants discussed the results of the counseling session with their husbands. On average, they rated their spouses as "somewhat" supportive and felt the process had placed "a little" strain on the marital relationship. A subsample of 20% of participants reported that their spouses had avoided discussing the issue and reported that the process placed some strain on the relationship. One month post-notification: only 1/14 participants were carriers (too small for statistical comparisons). All but one of the women had disclosed results to their

spouses. Whereas marital strain imposed by testing was relatively low in the majority, 30% stated their spouses "somewhat avoided" discussing the testing and half rated their spouses as "somewhat supportive" (3 on a 5 point Likert scale).

BODY

Technical Objectives

We are conducting a prospective study to evaluate the impact of genetic testing for breast-ovarian cancer susceptibility on the marital relationships of women at risk as well as the impact upon the quality of life of their husbands. This study is a companion proposal to an ongoing, DOD-funded prospective study that is evaluating the outcomes of genetic testing for breast-ovarian cancer susceptibility on women from hereditary breast cancer families. The proposed study extends the ongoing DOD-funded study to examine the impact of genetic testing upon the marital relationship and the psychosocial impact on the spouse.

Aim 1: To evaluate the short- and long-term impact of BRCA1/2 testing on psychological distress (both general and cancer-specific) of husbands of participants in genetic testing programs. At 1- and 6-months post-notification, husbands of women who have a confirmed BRCA1/2 mutation will have increased psychological distress (general and cancer-specific) compared with husbands of non-carriers (NC) and test decliners (TD). At 12 months, there will be no differences between the three groups.

Aim 2: To evaluate the short- and long-term impact of BRCA1/2 testing on the marital relationships of participants and husbands, and examine whether marital satisfaction is an early predictor of psychological morbidity among participants in genetic testing programs and their spouses. It is hypothesized that, at 1- and 6-months post-notification, husbands of women who have a confirmed BRCA1/2 mutation (Mc) will have decreased marital satisfaction compared with husbands of non-carriers (Nc) and test decliners (Td). At 12 months, there will be no differences between the three groups. It is hypothesized that, for participants with high levels of marital satisfaction at baseline, marital satisfaction will not change significantly from pre- to post-notification (Mc, Nc, Td). For participants with low levels of marital satisfaction at baseline, carriers' marital satisfaction will decrease over the one year follow-up whereas noncarriers' and decliners' marital satisfaction will not change over the 1 year follow-up. Similar predictions are made for husbands.

Aim 3: To examine the association between spouse responses during the testing process and carriers' distress post-notification. Carrier women who evidence high levels of cancer-related worries and experience more constraints in their ability to talk to their spouse about the testing experience will evidence more psychological distress and lower marital satisfaction at 6- and 12-months post-notification.

Methods

Overview of Study Design

Parent DOD study. In this prospective longitudinal study, eligible women are invited to participate in a baseline telephone interview. Subsequently, they are invited to participate in a Pre-Test education session and are offered a test for the BRCA1 mutation known to be segregating in their family. The results of this test are presented at an individual genetic counseling session. All women receive follow-up phone interviews at 1-, 6-, and 12-months post-disclosure. Persons who agree to participate in the study but decline Pre-test education and/or mutation status determination receive the same telephone interviews. Analyses compare mutation carriers, noncarriers and participants who decline testing.

Proposed Study. We propose to extend the parent study to examine psychological impact of testing on spouses of these women as well as examine impact on the marital relationship from patient and spouse perspectives.

Participants

Persons eligible for this study are married females, ages 18 and older, who are member of HBOC families in which a disease conferring mutation has been identified, and their spouses. We estimate that about 30% of the sample will be affected (statistical analyses will control for status-affected vs. at-risk). Subjects are ineligible for this study if either they have a psychiatric or cognitive disorder which precludes informed consent.

Based on current figures for accrual for the ongoing study, 5 women per week will be eligible for participation. Study accrual will span two and one half years. Seventy percent of the pool of 650 women will be married (N= 455). Of these 455, current figures from the ongoing study suggest that 30% (137) will decline mutation status testing. If 318 women elect to receive test results, about 145 (32%) should be mutation carriers and 172 (38%) noncarriers (there are more non-carriers since some subjects will be at 25% risk). Ten percent of participants drop out of the study by the one year follow-up, with a final sample size of 410: N, carrier group=130, N, noncarrier group=152, N, decline testing=130. Women will be eligible for the study if their spouse declines participation (this is relevant to sample size for Aim 3). From the PI's ongoing study of couples with cancer, it is anticipated that 10% of spouses will decline participation. Thus the final sample size of husbands is 370 (of which 110 are carrier couples). Given our current sample, we expect that 65% of subjects will be white, 25% African American, 5% Hispanic, and 5% Asian/Pacific Islander or Native American.

Procedures

Identification of subjects. Procedures for identifying eligible HBOC families are described in detail in the funded DOD parent grant. We will provide an abbreviated description of study procedures and focus on spousal recruitment procedures.

Recruitment of participants. Procedures are being used successfully in the ongoing study that forms the basis for this proposal. Informed consent procedures are consistent with the guidelines of the NIH/National Center for Human Genome Research (NCHGR) Cancer Studies Consortium, of which Dr. Lerman is a member.

Recruitment of spouses. The introductory letter will include a description of the desire for spouse participation and a rationale for the inclusion of spouses in the study. When women are contacted for oral consent for the baseline telephone interview, permission to contact the spouses will be obtained. It will be stressed that permission to contact spouses is not a requirement for participation in the individual portion of the study. A letter will be sent to spouses immediately after permission is given to contact them. Written informed consent for the telephone interviews with the spouses will be obtained.

Baseline Telephone Interview: Women. In addition to the information already being collected (cancer-specific and general distress), the following will be administered: plans to disclose test results to the spouse, strain of testing process on marital relationship, perceived constraints in talking to the spouse, and marital satisfaction.

A Pre-Test Standard Education Session will be conducted within the next four weeks among consenting subjects. Written consent is obtained from all subjects prior to the education session. A genetic counselor conducts all sessions, under the supervision of a medical oncologist and Dr. Lerman (See Appendix for topics). **Determination of Carrier Status, Genetic Counseling/Disclosure of Genetic Test Results, Cancer Prevention/Surveillance**

Recommendations. Mutation status tests and counseling are offered to all high risk females. Informed consent, procedures and topics covered in the Disclosure session are described in the Appendix. At the patient's discretion, a spouse or companion may be present at this meeting (controlled for in statistical analysis). **Follow-up Genetic Counseling** is conducted by telephone about two weeks after disclosure of mutation status (only for those subjects who received test results) (see Appendix). **Follow-up Telephone Interviews** are conducted at 1-, 6- and 12-months after the individual genetic counseling session for subjects who received results of mutation testing. Subjects who declined to be tested will be contacted for follow-up at these timepoints after the Pre-Test Education date of their index family member (proband). Telephone interviews are conducted (by blinded interviewers) to reassess measures included in the ongoing study.

Data collection procedures: Spouses. After spouses give written consent for the telephone interview, they will be administered surveys by phone at the same times as the wives are

administered surveys: baseline, 1-, 6- and 12-months after the individual genetic counseling session for spouses of subjects who received the test results.

Telephone interviews will be supervised by Dr. Audrain (women) and Dr. Manne (spouses). Telephone interviews are used successfully in ongoing data collection. At the end of the interview, women are invited to attend a Pre-Test Education session. Those who decline are asked if we may contact them for follow-up interviews. In the ongoing study, there is 80% compliance with interviews, even among decliners.

Measures given to both partners, all time points: 1) Cancer-Specific Distress: The Impact of Events Scale (IES) is a 21 item scale that has intrusion and avoidance subscales; 2) Hopkins Symptom Checklist-25: a 25 item Likert scale indicating severity of anxiety and depression; 3) Dyadic Adjustment Scale: widely-used 32-item scale assessing marital satisfaction (Kagan et al., 1991). Subscales include cohesion, satisfaction, affection and consensus; 4) Marital Strain: 2-items assessing marital strain during testing process. Additional measures for women: 1) Baseline: a) whether decision to seek genetic testing was discussed with spouse; b) whether subjects plan to disclose test results to spouse; c) constraints in talking with husband about breast cancer and testing (5 items; adapted from Lepore's (Lepore et al., 1996) scale); 2) Post-notification: a) whether or not test results were disclosed; b) spouse supportive/unsupportive responses during discussion; c) if no disclosure was made, whether or not disclosure is planned; d) constraints. Additional measures for husbands: 1) Baseline: a) whether decision to test was discussed; 2) Post-notification: a) whether test results were disclosed; 3) All time points: Cancer specific distress/concerns (in addition to IES): Worries about testing effects on: a) children; b) childbearing decisions; c) worry about possible cancer diagnosis; d) worry about caregiving responsibilities should the wife be diagnosed.

Data Analysis: **Hypothesis 1:** The two dependent measures (husband IES, HSCL) will be examined individually (i.e., univariate analyses) and together (multivariate analyses) using multifactor fixed effect ANOVA and ANCOVA with blocking on family (women are from hereditary families). The 1-, 6-, and 12-month post-notification responses will first be analyzed separately with baseline response used as a covariate. The two dependent variables will be analyzed together using repeated measures ANOVA, with the between groups factor as test group (Mc, Nc, Td). The independent variables will include: (1) whether or not the woman is affected and (2) whether the husband was present during counseling and disclosure of test results. We will also explore the influence of other relevant sociodemographic variables and interactions (e.g. husband education, ethnicity) are explored. These tests of interaction effects will identify variables which modify the impact of testing among husbands of carriers, noncarriers, and test decliners. **Hypothesis 2:** The analysis of DAS scores of husbands and wives will be analyzed separately using the same ANOVA and ANCOVA approaches outlined above for husband distress. For the second question, we will examine the influence of marital satisfaction at baseline on post-notification marital satisfaction of women and husbands. High and low marital satisfaction will be determined by a median split on the baseline DAS variable. A repeated measures MANOVA will be conducted separately for the two indicators of marital satisfaction (general

marital satisfaction and marital strain). Baseline general marital satisfaction will be entered into the analysis. We will examine differences in marital satisfaction over time between the three groups (Mc, Nc, Td) using ANOVA approaches outlined above, examining the interaction between carrier status and baseline marital satisfaction. It is predicted that carriers and husbands with low marital satisfaction at baseline will evidence more marital dissatisfaction post-notification than carriers with high marital satisfaction or noncarriers and test decliners with low or high marital satisfaction. **Hypothesis 3:** This analyses will be conducted on women who are carriers. We will use separate regression analyses with women's psychological distress and marital satisfaction at 1-, 6- and 12-months post-notification as dependent variables. We enter first into the equation sociodemographic variables which predict distress and marital satisfaction. Next, we will enter: 1) distress at baseline, 2) intrusive thoughts about cancer, 3) constraints in talking with the husband, 4) the interaction term between intrusive thoughts and constraints (centered). It is anticipated that the interaction term will be significant. **Power Analysis:** The design of the study is essentially one of clustered sampling, since study subjects are identified on the basis of family membership. Outcome measures will be considered at the four time points. Between participant factors will include test result (carrier, noncarrier, decliners). An interaction effect would reveal a different course of psychological responses over time. *This is not done yet.*

Preliminary Results

To date, gene mutation test results have not been received by the majority of patients. Thus, we report several sample means on outcome variables. Additionally, statistical significance has not been determined yet because of the small sample size. The preliminary analysis includes baseline data from 35 husbands (demographics and outcome variables) and 49 wives (outcome variables only.)

Findings

Sample Characteristics for Husbands

The mean age of the husbands was 50.65 ± 12.24 years. All of the husbands had completed high school. Fifty-three percent of the husbands had degrees from graduate school. The husbands had been married 3.5 to 49 years (mean time=20.3 years.) Ninety-four percent of the sample were Caucasian.

Results: General Psychological Distress, Cancer Specific Psychological Distress, and Marital Satisfaction

Means and standard errors for the main variables of interest are reported in the table below.

Lower scores for *cancer specific avoidance, cancer specific intrusive thoughts, psychological distress, state anxiety, and trait anxiety* indicate better psychological profiles. **Higher** scores for *marital adjustment* indicates a greater satisfaction with the marital relationship.

In this section we present mean levels of psychological distress and marital satisfaction for both partners (Table 1).

Table 1. Means and standard errors of the variables of interest by subgroup and time of questionnaire

Variables of Interest	Baseline		1-Month Follow-Up
	Wives (n=49)	Husbands (n=35)	Husbands (n=6)
Cancer Specific Avoidance	9.33 (1.07)	6.71 (1.45)	6.33 (2.43)
Cancer Specific Intrusive Thoughts	10.09 (1.25)	4.97 (0.87)	9.00 (2.19)
Psychological Distress	39.12 (2.53)	33.55 (1.29)	35.83 (2.68)
State Anxiety	-----	11.63 (2.03)	11.33 (4.11)
Trait Anxiety	-----	6.30 (1.91)	-----
Marital Adjustment	115.44 (4.23)*	98.87 (2.90)	121.50 (7.49)

*n=26

The husbands scored lower than the wives (n=49) on each measure for which there was comparative data at baseline. Wives were more likely to use avoidance, have intrusive thoughts, and experience psychological distress compared to the husbands. Wives also rated higher marital satisfaction.

The men scored lower at baseline (n=35) on four of the measures of interest (the presence of intrusive thoughts, general psychological distress, state anxiety, and marital adjustment) than at 1-month follow-up (n=6). Only the mean score on the avoidance measure was higher at baseline compared to the 1-month follow-up, indicating an increase in the use of avoidance after learning of the wife's genotype. The degree of state (acute) anxiety in the husbands at baseline also was greater than the degree of trait (chronic) anxiety.

Obstacles to Beginning Research-Related Tasks

Due to delays in the early phase of the study, our study recruitment is five months behind schedule. The delay was related to two factors:

(1) The principal investigator was not informed by the Research Administration of Fox Chase that a notice of grant award was given May 4, 1998. This date was four months earlier than the anticipated date of September, 1998 which was listed on the DOD award application. We were not notified of the study's approval status by the Fox Chase Cancer Center Research Administration until July, 1998.

(2) After revisions of the study protocol were submitted to the Institutional Review Board at FCCC, final IRB approval to begin the study was not granted until October 12, 1998 due to a month (August) vacation of the IRB chair, Dr. T. London. We began recruitment immediately after notification, but we are still trying to attain our projected numbers of completed interviews for this point in our time schedule.

Statement of Work

Task 1 -- Month 1

Refine measures and train interviewers; plan communication between the two study sites (Georgetown and Fox Chase.)

- a. The measures have been finalized.
- b. Questionnaires have been xeroxed.
- c. Resident assistants have been trained to conduct the interviews.
- d. The procedures for sharing patient information between the two study sites has been developed and tested.

Task 2 -- Months 2-29

Subject recruitment and data collection as of March 25, 1999

- a. Seventy-eight patients (wives) have been approached at Georgetown University for interest in participating in the study. Sixty (77%) of these women permitted us to contact their husbands for participation in the Fox Chase Cancer Center Study.
- b. Thirty-four husbands successfully have completed baseline surveys on marital satisfaction, impact of genetic testing on the marital relationship, and constraints.
- c. Sixty husbands have been approached to participate in the study. Of these, 11 refused to participate, and 2 dropped out of the study. Reasons for refusal: (1) the wife had received the results of genetic testing before the husband had completed the baseline questionnaire (n=2); (2) the husbands felt that the questionnaire involved issues that were personal (n=3); (3) the wives decided against completing the genetic testing procedure (n=2); and (4) the husbands were not interested in participating (n=4).
- d. One month follow-up surveys have been administered to 6 husbands and 6 patients (wives).
- e. Interviews have been supervised by Drs. Manne (FCCC) and Audrain (GUMC) on a weekly basis.

Task 3 -- Months 1-3

Data screens set up; data entry begun at Fox Chase

- a. Data at GUMC are collected using Computer Assisted Telephone Interviewing (CATI) and screens have been established at that site for this purpose.

- b. Data at FCCC are not collected using CATI. Data entry screens have been established.
- c. Data entry has been ongoing for several months at Fox Chase Cancer Center.

Task 4 -- Months 29-36

Completion of follow-up interviews

- a. Follow-up interviews will be completed for accrued patients and spouses.

Task 5 -- Months 30-36

Data Analyses

- a. Encrypted data will be transferred by e-mail from GUMC to FCCC.
- b. Data analyses will be conducted to test the impact of testing and declining upon partners' marital satisfaction, marital strain, and the psychological distress of husbands.

Discussion

The results of the preliminary analysis suggest that husbands may experience less psychological distress than wives at the baseline assessment (pre-mutation disclosure). This finding likely is explained by the fact that the wives are undergoing genetic testing. However, the level of distress may increase for the husbands within one month of learning of the wife's mutation status results. Further analysis when more disclosures have been completed will elucidate the role of mutation status outcome (MC, TD, NC) in these outcome variables.

CONCLUSIONS

Due to the small sample size that has been acquired thus far, it is too early in the data collection process to make conclusions. However, data collection is progressing smoothly. Within the next few months, general trends or patterns in the data should be obvious. Significant differences by groups or by the time of questionnaire administration will be determined at that time.

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APPENDIX

Appendix

Study Measures Key

Measures Administered to Both Partners

- A. General Psychological Distress -- Hopkins Symptom Checklist -- 25
- B. Cancer Specific Psychological Distress -- Impact of Events Scale
- C. General Marital Satisfaction -- Dyadic Adjustment Scale
- D. Cancer Specific and General Anxiety -- State-Trait Anxiety Inventory
- E. Marital Strain Imposed by Testing Process

Measures Administered Only to Wives

- F. Baseline
Decision to seek testing discussed with husband
Plans to disclose test results with husband
- G. Follow Ups
Has decision to test been discussed?
How did he respond?
Plans to disclose in the future
- H. All Time Points
Constraints Measure

Measures Administered Only to Husbands

- I. Baseline
Has wife discussed decision to seek testing?
Breast cancer concerns
- J. Follow Ups
Has wife discussed results with genetic testing?
Breast cancer concerns

Measures Administered to Both Partners

HSCL-25

Instructions: Listed below are some symptoms of strain that people sometimes have. Please read each one carefully and circle the number that best reflects how much that symptom has bothered you during the past month.

	Not at All	A Little	Quite a Bit	Extremely
1. Suddenly scared for no reason.....	1	2	3	4
2. Feeling fearful.....	1	2	3	4
3. Faintness, dizziness, or weakness.....	1	2	3	4
4. Nervousness or shakiness inside.....	1	2	3	4
5. Heart pounding or racing.....	1	2	3	4
6. Trembling.....	1	2	3	4
7. Feeling tense or keyed up.....	1	2	3	4
8. Headaches.....	1	2	3	4
9. Spells of terror or panic.....	1	2	3	4
10. Feeling restless, can't sit still.....	1	2	3	4
11. Feeling low in energy, slowed down.....	1	2	3	4
12. Blaming yourself for things.....	1	2	3	4
13. Crying easily.....	1	2	3	4
14. Loss of sexual interest or pleasure.....	1	2	3	4
15. Poor appetite.....	1	2	3	4
16. Difficult falling asleep, staying asleep.....	1	2	3	4
17. Feeling hopeless about the future.....	1	2	3	4
18. Feeling blue.....	1	2	3	4
19. Feeling lonely.....	1	2	3	4
20. Feeling trapped or caught.....	1	2	3	4
21. Worrying too much about things.....	1	2	3	4
22. Feeling no interest in things.....	1	2	3	4
23. Thoughts of ending your life.....	1	2	3	4
24. Feeling everything is an effort.....	1	2	3	4
25. Feelings of worthlessness.....	1	2	3	4

Revised RIES

Instructions: Below is a list of comments made by some people who have cancer in their family. Please tell how frequently these comments were true for you **DURING THE PAST 7 DAYS**. Would you say this occurred....²²
not at all, rarely, sometimes, or often?

	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.....	0	1	3	5
2. I avoided letting myself get upset when I thought about it or was reminded of it.....	0	1	3	5
3. I tried to remove it from memory.....	0	1	3	5
4. I had trouble concentrating.....	0	1	3	5
5. Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.....	0	1	3	5
6. I had trouble falling asleep or staying asleep, because of pictures or thoughts about it that came into my mind.....	0	1	3	5
7. I had waves of strong feelings about it.....	0	1	3	5
8. I had dreams about it.....	0	1	3	5
9. I felt watchful and on guard.....	0	1	3	5
10. I stayed away from reminders of it.....	0	1	3	5
11. I felt as if it hadn't happened or it wasn't real.....	0	1	3	5
12. I tried not to talk about it.....	0	1	3	5
13. Pictures about it popped into my mind.....	0	1	3	5
14. I was jumpy and easily startled.....	0	1	3	5
15. Other things kept making me think about it.....	0	1	3	5
16. I felt irritable and angry.....	0	1	3	5
17. I was aware that I had a lot of feelings about it, but I didn't deal with them.....	0	1	3	5
18. I tried not to think about it.....	0	1	3	5
19. Any reminder brought back feelings about it.....	0	1	3	5
20. My feelings about it were kind of numb.....	0	1	3	5
21. I found myself acting or feeling like I was back at that time.....	0	1	3	5

PLEASE REMEMBER TO CONSIDER YOUR FEELINGS OVER THE PAST MONTH:

	All the time	Most of the time	More often than most	Occasionally	Rarely	Never
16. How often do you discuss or have you considered divorce, separation of terminating your relationship _____	_____	_____	_____	_____	_____	_____

17. How often do you or your mate leave the house after a fight? _____	_____	_____	_____	_____	_____	_____
--	-------	-------	-------	-------	-------	-------

	All the time	Most of the time	More often than most	Occasionally	Rarely	Never
18. In general, how often do you think that things be- tween you and your partner are going well? _____	_____	_____	_____	_____	_____	_____

19. Do you confide in your mate? _____	_____	_____	_____	_____	_____	_____
---	-------	-------	-------	-------	-------	-------

20. Do you ever regret that you married? (or live together) _____	_____	_____	_____	_____	_____	_____
---	-------	-------	-------	-------	-------	-------

21. How often do you and your partner quarrel? _____	_____	_____	_____	_____	_____	_____
---	-------	-------	-------	-------	-------	-------

22. How often do you and your mate "get on each other's nerves?" _____	_____	_____	_____	_____	_____	_____
--	-------	-------	-------	-------	-------	-------

	Every Day	Almost Every Day	Occasionally	Rarely	Never
23. Do you kiss your mate? _____	_____	_____	_____	_____	_____

PLEASE REMEMBER TO CONSIDER YOUR FEELINGS OVER THE PAST MONTH:

	All of Them	Most of Them	Some of Them	Very few of Them	None of Them
24. Do you and your mate engage in outside interests together?	_____	_____	_____	_____	_____

How often would you say the following events occur between you and your mate?

	Never	Less than once a month	About twice a month	About twice a week	Once a day	More often
25. Have a stimulating exchange of ideas	_____	_____	_____	_____	_____	_____
26. Laugh together	_____	_____	_____	_____	_____	_____
27. Calmly discuss something	_____	_____	_____	_____	_____	_____
28. Work together on a project	_____	_____	_____	_____	_____	_____

These are some things about which couples sometimes agree and sometimes disagree. Indicate if either item below caused differences of opinions or were problems in your relationship during the past month. (Check yes or no)

	Yes	No	
29. _____	_____	_____	Being too tired for sex.
30. _____	_____	_____	Not showing love.

PLEASE REMEMBER TO CONSIDER YOUR FEELINGS OVER THE PAST MONTH:

31. How would you describe the degree of happiness, all things considered, of your relationship? "Happy" represents the degree of happiness of most relationships. Please circle the letter which best describes the degree of happiness of your relationship.

A..... Extremely unhappy
B..... Fairly unhappy
C..... A little unhappy
D..... Happy
E..... Very happy
F..... Extremely happy
G..... Perfect

32. Please check one of the following statements which best describes how you feel about the future of your relationship.

_____ I want desperately for my relationship to succeed, and would go to almost any length to see that it does.

_____ I want very much for my relationship to succeed, and will do all I can to see that it does.

_____ I want very much for my relationship to succeed, and will do my fair share to see that it does.

_____ It would be very nice if my relationship succeeded, but I can't do much more than I am doing now to help it succeed.

_____ It would be nice if it succeeded, but I refuse to do any more than I am doing how to keep the relationship going.

_____ My relationship can never succeed, and there is no more that I can do to keep the relationship going.

SELF-EVALUATION QUESTIONNAIRE **STAI Form Y-1**

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then check in the appropriate square to the right of the statement to indicate how you feel right now, that is, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately So	Very Much so
1. I feel calm.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel secure.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I am tense.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I feel strained.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel at ease.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I feel upset.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I am presently worrying over possible misfortunes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I feel satisfied.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I feel frightened.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I feel comfortable.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I feel self-confident.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I feel nervous.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I am jittery.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I feel indecisive.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I am relaxed.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I feel content.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. I am worried.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. I feel confused.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I feel steady.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I feel pleasant.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SELF-EVALUATION QUESTIONNAIRE STAI Form Y-2

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then check in the appropriate square to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

	Almost Never	Some- times	Often	Almost Always
21. I feel pleasant.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. I feel nervous and restless.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. I feel satisfied with myself.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. I wish I could be as happy as others seem to be.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. I feel like a failure.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. I feel rested.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. I am "calm, cool and collected".....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. I feel that difficulties are piling up so that I cannot overcome them.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. I worry too much over something that doesn't really matter.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. I am happy.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. I have disturbing thoughts.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. I lack self-confidence.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. I feel secure.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. I make decisions easily.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. I feel inadequate.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. I am content.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Some unimportant thought runs through my mind & bothers me.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. I take disappointments so keenly that I can't put them out of my mind.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. I am a steady person.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40. I get in a state of tension or turmoil as I think over my recent concerns and interests.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Marital Strain Survey

Instructions: Please answer the following questions, using the scales given.

In the past month....

1. To what degree has the process of genetic testing placed a strain upon your relationship with your wife?

1	2	3	4	5
No strain	A little strain	Some strain	Much strain	Extreme strain

2. To what degree has the process of genetic testing *negatively affected* your relationship with your wife?

1	2	3	4	5
Not at all	A little	Somewhat	A lot	Extremely

3. To what degree has the process of genetic testing *positively affected* your relationship with your wife?

1	2	3	4	5
Not at all	A little	Somewhat	A lot	Extremely

4. To what degree has the process of genetic testing made your relationship with your wife closer?

1	2	3	4	5
Not at all	A little	Somewhat	A lot	Extremely

Measures Administered Only To Wives

Marriage and Genetic Testing

31

1. Did you discuss the decision to seek genetic testing for breast cancer with your spouse (circle one)?

YES

NO

2. Do you plan to disclose your test results, should you chose to receive this information, with your husband?

YES

NO

Have not decided yet

MARRIAGE AND GENETIC TESTING

1. Have you discussed the results of the genetic testing with your husband? (Circle one)

YES

NO

If you answered YES to this question, please continue. If you answered NO, please skip to question 2.

2. How did he respond? When providing your ratings, please use the following scale:

1	2	3	4	5
Not at all		Somewhat		Very much

_____ He was supportive and appeared to understand and empathize with my reactions.

_____ He avoided discussing this issue with me and withdrew from me when we discussed it.

3. If you have not discussed the test results, do you plan on disclosing the results of the genetic testing to him in the future? (Circle one)

YES

NO

DO NOT KNOW

4. If you do not plan or you do not know whether you will disclose your test results, what prevents you from sharing this information with him? Please use the following scale in making your rating:

1	2	3	4	5
A little		Somewhat		Extremely

_____ I do not think he needs to know this information.

_____ He asked not to be told.

_____ I am worried about the impact this information would have upon him.

_____ I am worried about the impact his would have on our relationship.

ANOTHER REASON (please describe): _____

Instructions: Following the results of your genetic testing, people will react in different ways. For example, some people want to talk about what has happened to them, while others do not. Please answer each question, indicating how frequently these comments were true for you. **DURING THE PAST WEEK INCLUDING TODAY.**

	Almost Never		Sometimes		Almost Always
1. How often have you wanted to talk about the genetic testing experience (your risk status, your worries, your feelings) with your husband?	1	2	3	4	5

Please answer the following questions pertaining to *your husband*.

- | | | | | | |
|--|------------|---|------|---|--------------|
| | Not at all | | Some | | A great deal |
| 2. How often did you actually talk with your husband about the genetic testing experience? | 1 | 2 | 3 | 4 | 5 |
| 3. How often did you share your concerns about the genetic testing experience with your husband? | 1 | 2 | 3 | 4 | 5 |
| 4. How often did you actually talk with people other than your husband about the genetic testing experience? | 1 | 2 | 3 | 4 | 5 |
| 5. How comfortable are you talking with your husband about the genetic testing experience? | 1 | 2 | 3 | 4 | 5 |
| 6. How comfortable are you sharing your thoughts and feelings with other family and friends? | 1 | 2 | 3 | 4 | 5 |

Measures Administered Only to Husbands

Disclosure Question

1. Did your wife discuss the decision to seek genetic testing for breast cancer with you?

(Circle one)

YES

NO

Disclosure Questions

1. Has your wife discussed the results of the genetic testing for breast cancer with you? (Circle one)

YES

NO

CONCERNS SCALE

Please rate how concerned you are about the following issues:

1. I worry about my children's cancer risk.

	1	2	3	4	5
No children	Fairly concerned	A little concerned	Somewhat concerned	Very concerned	Extremely concerned

2. I worry about our decision to have more children in the future.

	1	2	3	4	5
We are not planning more children	Fairly concerned	A little concerned	Somewhat concerned	Very concerned	Extremely concerned

3. I worry about the possibility of my wife being diagnosed with cancer in the future.

1	2	3	4	5
Fairly concerned	A little concerned	Somewhat concerned	Very concerned	Extremely concerned

4. I worry about having to become responsible for taking care of my wife and family should she be diagnosed with cancer.

1	2	3	4	5
Fairly concerned	A little concerned	Somewhat concerned	Very concerned	Extremely concerned

Consent Form

IRB#98-802
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Version 3.0, September 17, 1998

INFORMED CONSENT FOR CLINICAL RESEARCH

SPOUSE INFORMED CONSENT

I am being asked to participate in a research study which will evaluate the impact of education and counseling about genetic testing for breast and/or ovarian cancer. I have been told that I have the option not to participate.

The nature of this study, the risks, inconveniences, discomforts, and other pertinent information about the study are explained below. I am urged to discuss any questions I have about this study with the staff members who explain it to me.

The title of this research study is: IMPACT OF BRCA1/2 TESTING ON MARITAL RELATIONSHIPS.

Purpose of the Research Study:

The study will examine the impact of genetic testing for an increased risk of breast and/or ovarian cancer on the marital relationships of women at risk, as well as the impact upon the quality of life of their husbands. Genetic testing for cancer risk can be stressful for both the woman at risk and her spouse. The investigators are interested in understanding these issues.

Description of the Research Procedures:

I understand that this study involves research. If I consent to participate, I will be asked to complete phone interviews at four different points in time. The first interview will occur prior to my wife's participation in an education session about the genetic testing. The three remaining interviews will be conducted at approximately 1-, 6-, and 12-month intervals following the session.

Each interview will ask questions about marital satisfaction, psychological well-being, and concerns about the impact of the genetic testing. Each interview should take approximately 30-45 minutes.

My spouse will also be asked to complete similar interviews. My responses to the interviews are completely confidential, as are my spouse's responses.

Other than time required for participation (a total of 2-3 hours over a 1 year period), this study will not involve changes in my daily activities.

Risks

This study involves research that presents minimal risk. While there are no physical risks/side effects involved in my participation, there is the possibility of psychological distress. It is possible that answering questions contained in the interview may be upsetting. Should I become upset, the principal investigator will be available to provide reassurance, and, if appropriate, a professional referral.

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Although unlikely, if I am injured as a result of my participation in this research study, emergency care, hospitalization, and outpatient care will be made available by the hospital and billed to me. No money will be provided by the hospital as compensation for a research-related injury.

Benefits

No guarantee is being offered that I will benefit from this study; however, the investigators have reason to believe that the information I provide will be beneficial to future couples undergoing genetic testing. Although the investigators hope that this research study will be of benefit to me, or that it will help others, they cannot say that it will help me directly.

If I wish, I will be informed of the results of this study when it is completed.

Financial Cost

Participation in this study will not involve any additional financial costs.

Confidentiality

My responses to these interviews are confidential. Both interviews and computerized data from the interviews will be kept confidential. I understand that my answers to the interviews will not be shared with my spouse without my express permission, and my spouse's answers to her interviews will not be shared with me without her permission.

I understand that there is a possibility that authorized individuals from government agencies such as the Food and Drug Administration, Office of Protection from Research Risks, U.S. Army Medical Research and Material Command may review my records as part of their responsibility to protect human subjects in research.

My name or any other personally identifying information will not be used in reports.

Questions

If I have questions about the research, or in the event of a research-related injury, I may contact the Institutional Review Board which is concerned with protection of participants in research projects. I may reach the Board office by calling (215)-728-2518, 9:00 am to 3:00 pm, Monday to Friday, or by writing the Institutional Review Board, Fox Chase Cancer Center, 7701 Burholme Avenue, Philadelphia, PA 19111.

I am free to ask questions at any time about these procedures and to ask for additional information. If I have questions, I can reach Dr. Sharon Manne, the psychologist conducting the study, at (215)-728-2896.

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Significant Findings

As the research progresses any significant new findings, beneficial or otherwise, will be told to me and explained as related to my case.

Right to Refuse or Withdraw

Participating in this study is voluntary. I may refuse to answer any specific question or interview items. I understand that I am free to withdraw my consent to participate in this study at any time. If I withdraw, there will not be penalty or loss of benefits.

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INFORMED CONSENT FOR CLINICAL RESEARCH

SPOUSE CONSENT

TITLE: IMPACT OF BRCA1/2 TESTING ON MARITAL RELATIONSHIPS

By signing below, I indicate that I have read this form, received acceptable answers to any questions, and willingly consent to participate. I will receive a copy of this form.

Date _____

Investigator's Signature _____

Date _____

Spouse's Signature _____

Name (Print) _____